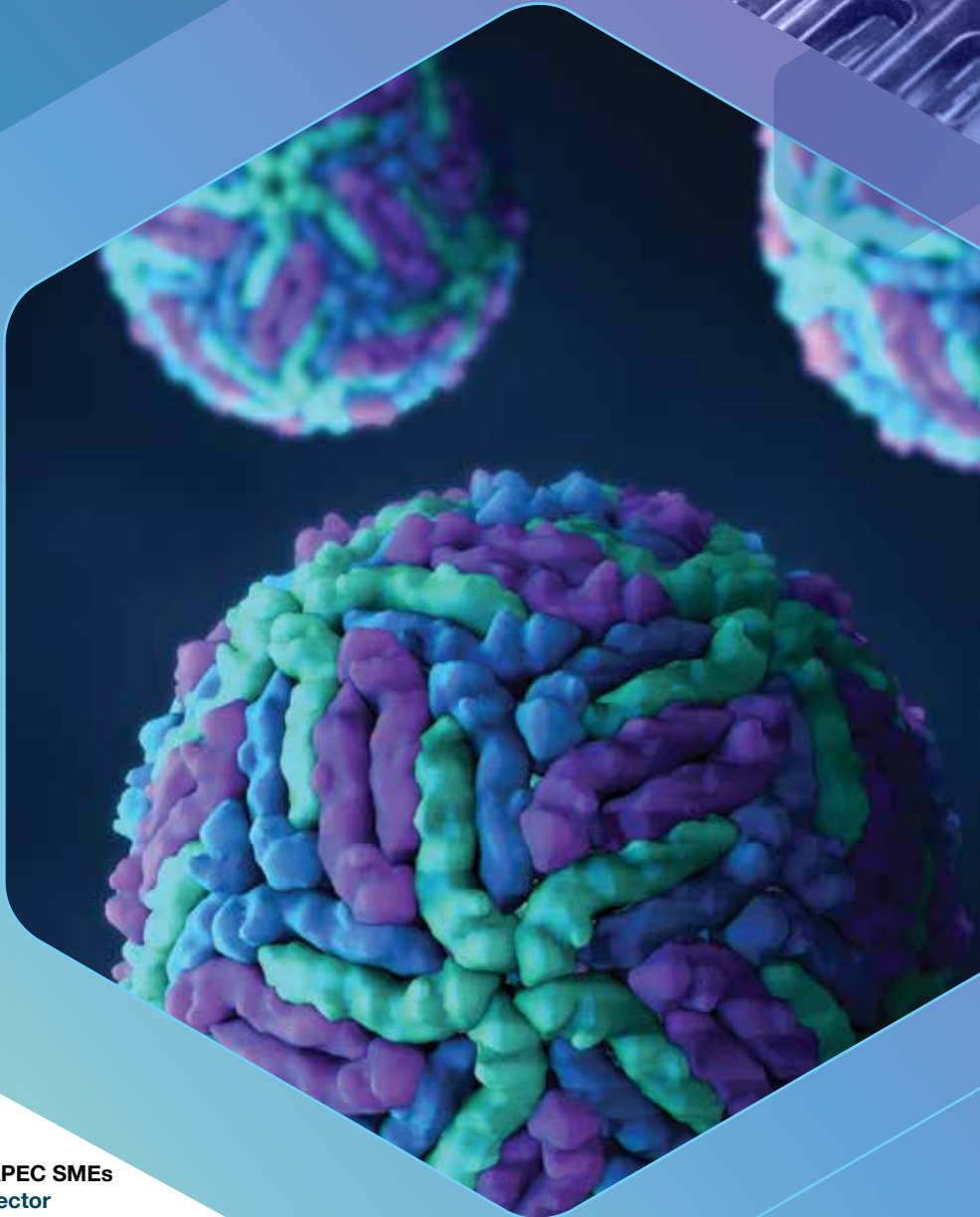


2019 Report on

Code of Ethics Implementation

by APEC Biopharmaceutical
Industry Associations



Asia-Pacific
Economic Cooperation

Business Ethics for APEC SMEs
Biopharmaceutical Sector

APEC Small and Medium Enterprises
Working Group (SMEWG)

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Executive Summary

Launched in 2010, the *Business Ethics for APEC SMEs* Initiative biopharmaceutical sector program actively supports the adoption and implementation of voluntary codes of ethics by the region's relevant industry associations. These associations include thousands of small and medium-sized enterprises that constitute the overwhelming majority of firms operating in the region's biopharmaceutical sector. Welcomed by APEC Economic Leaders and Ministers, this Initiative – the largest public-private partnership of its kind in the world – realizes the best practices set by the APEC Mexico City Principles in 2010 through implementation of the actions set forth in the APEC Nanjing Declaration to Promoting Ethical Environments in the Medical Device and Biopharmaceutical Sectors.

Monitoring and evaluation of code adoption and implementation by the APEC region's biopharmaceutical industry associations serves as one of the Initiative's core activities. This is done through an annual survey program extended to every known biopharmaceutical industry association in the region. To-date, the Initiative monitors 71 biopharmaceutical industry associations that represent a significant majority of the regional biopharmaceutical economy.

These annual surveys are divided into two components: code of ethics adoption and code of ethics implementation.



CODE ADOPTION

Only 12 of the APEC region's biopharmaceutical industry associations (17%) are not known to have adopted a high-standard code of ethics or are not known to be working toward one by 2020. This represents a seismic change since the *Business Ethics for APEC SMEs Initiative* was launched in 2010, when over 40 of the region's biopharmaceutical industry associations (62%) were not known to have adopted a high-standard code of ethics. In 2019, 19 APEC economies have broad sector coverage by a code of ethics, compared with less than half in 2012. SMEs constitute an overwhelming majority of the total membership across the region's biopharmaceutical industry associations. The APEC Nanjing Declaration calls for universal code of ethics adoption by all biopharmaceutical industry associations.

CODE IMPLEMENTATION

For the 56 biopharmaceutical industry associations (and the three progressing toward a new code in 2020) across the APEC region that have adopted a code of ethics, the *Business Ethics for APEC SMEs Initiative* actively monitors implementation with success indicators in four main areas: governance, alignment, member adherence, and external engagement.

In 2019, code of ethics governance by the region's biopharmaceutical industry associations remains strong across a full range of success indicators, with the main challenge remaining routine training and one-on-one assistance to member companies. Alignment with the APEC Mexico City Principles also remains very strong across the APEC region. Attention is warranted to a rapid expansion in the number of associations planning to undertake code amendments over the next year, which is nearly double the number of associations that undertook amendments over the past two years.

Of the 56 biopharmaceutical industry associations with an adopted code of ethics, 39 (70%) report a majority of their member

enterprises adhere to the code in their daily business practices. However, data from the 2019 survey demonstrates that those associations reporting lower member adherence contain the vast majority of SMEs. This could explain why 83% of associations with a code reported interest in the Initiative offering a program to support SME leaders implement ethical business practices.

Interest by biopharmaceutical industry associations to engage with external stakeholders across the health system on their codes of ethics hit a new record, aided by the further elaboration of Consensus Frameworks across the APEC region. This response also aligns with several new records in the number of associations reporting communication directly with other stakeholders on the code. Despite these improvements, as further indicated in code governance indicators, the region saw a decline in the number of associations reporting collaboration on ethics training with other stakeholders. Importantly, biopharmaceutical industry associations continue to engage with governments on their codes of ethics more than any other stakeholder and 95% support the identification of government strategies to support ethical companies.

To learn more about the initiative, please visit <http://mcprinciples.apec.org>

Note: The data presented in this Report is based upon the survey responses provided by the APEC region's biopharmaceutical industry associations. The Initiative does not conduct audits of the region's industry associations or their member companies.



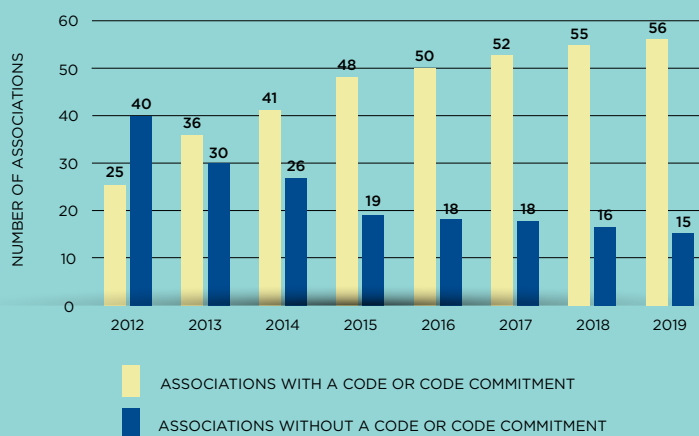
PART 1

Code Adoption

The *Business Ethics for APEC SMEs Initiative* tracks code adoption or code commitment by 71 biopharmaceutical industry associations located across the APEC region. In 2019, 56 or over 75% of these associations report having a code of ethics or code commitment in alignment with the APEC Mexico City Principles, impacting nearly 10,000 member companies of which over 6,000 are SMEs. Since this Initiative's capacity-building work commenced in 2012, 31 associations have launched a new code or code commitment where it did not previously exist, more than doubling the number of codes of ethics in the region.

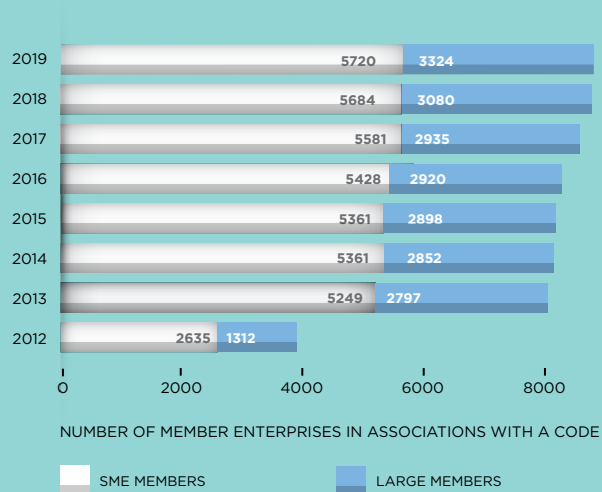
The remaining 15 biopharmaceutical industry associations without a code of ethics are located in seven APEC economies: Chile; Hong Kong, China; Korea; Mexico; Singapore; Russia; and Chinese Taipei, representing nearly 800 member companies. At least three of these associations based in Hong Kong, China and Chinese Taipei are progressing toward a new code in 2020.

INDUSTRY ASSOCIATIONS WITH A CODE OR CODE COMMITMENT

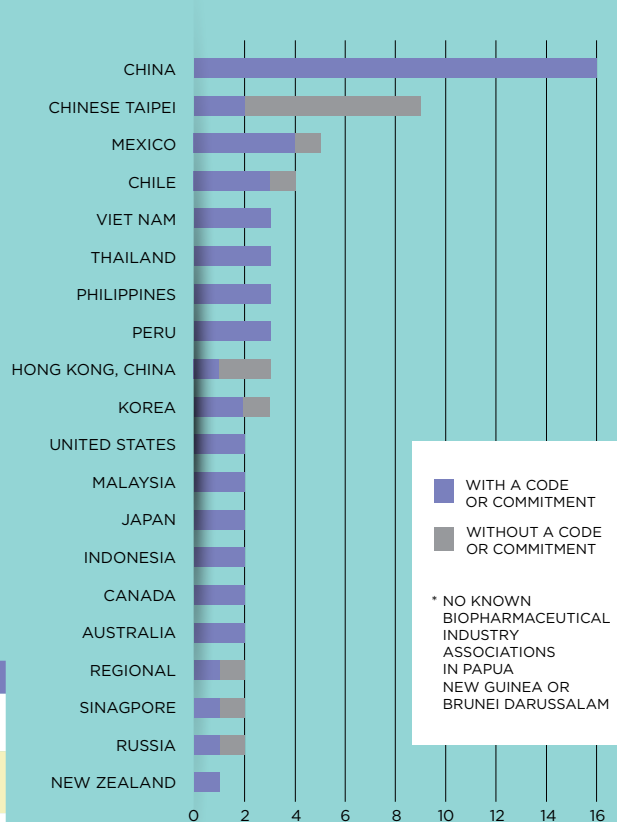


STATUS REPORT	2012	2019
Associations with a Code/Code Commitment:	25	56 (up 31)
Total Member Enterprises:	3,900+	9,800+ (up 5,900+)
SME Members:	2,600+	6,200+ (up 3,600+)

COMPANY MEMBERSHIP IN ASSOCIATIONS WITH A CODE OF ETHICS OR CODE COMMITMENT



CODE STATUS BY ECONOMY - 2019 DATA*



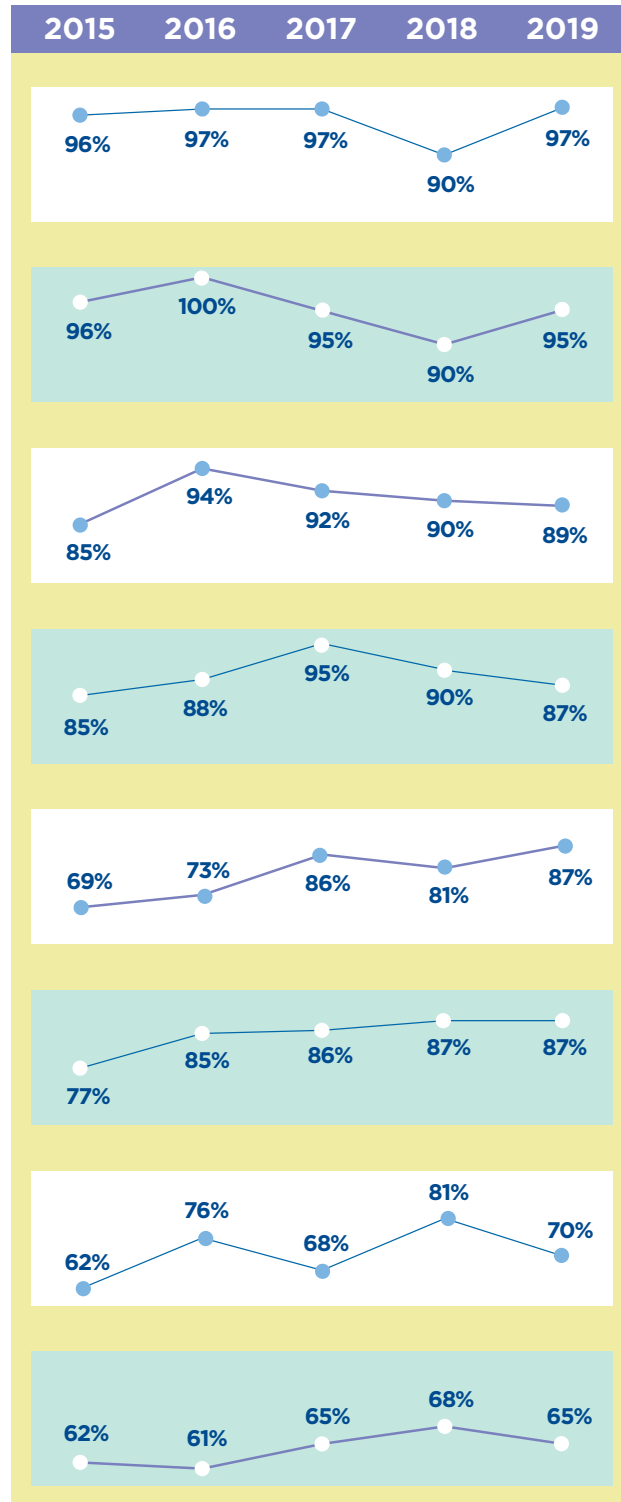
* NO KNOWN BIOPHARMACEUTICAL INDUSTRY ASSOCIATIONS IN PAPUA NEW GUINEA OR BRUNEI DARUSSALAM

PART 2

Code Implementation

CODE GOVERNANCE

Industry association codes are strong tools to disseminate and harmonize ethical business practices among enterprises within and across APEC economies. However, codes can only serve as an effective tool if robust governance is in place by the association and its members. This Initiative's success indicators in effective code governance saw little change over the past year, with a majority of associations continuing to report positive results. A record high was indicated in the number of associations with sufficient resources to support code maintenance, promotion, and implementation (87%). There was an 11% decrease in the number of associations providing one-on-one assistance to members seeking to align their business practices with the code (70%). And the number of associations offering one or more code of ethics training to members remains the lowest indicator (65%). The expanding gap between associations reporting sufficient resources and those providing one-on-one assistance or offering ethics trainings could suggest there is a need for associations to elevate their ability to provide capacity-building, especially for SMEs.



Associations that distributed the code to members for input before adoption

Associations that distributed the code to all members within the last two years

Associations that have designated staff or a member to oversee code maintenance, promotion, and implementation

Associations with procedures in place to review the code and ensure it is up-to-date

Associations with sufficient resources to support code maintenance, promotion, and implementation

Associations with a code complaint or violation procedure

Associations that provide one-on-one assistance to members seeking to align their business practices with the code

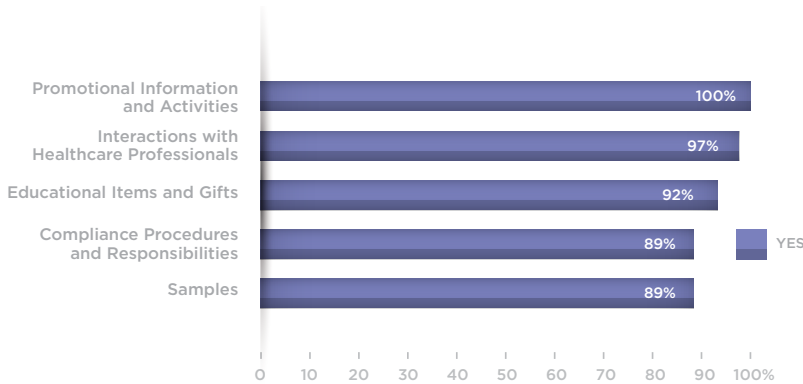
Associations who offer one or more code of ethics training to members

CODE ALIGNMENT WITH THE APEC MEXICO CITY PRINCIPLES

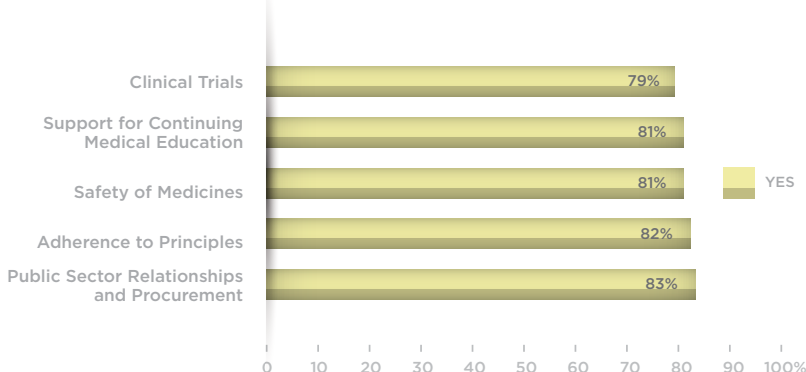
Endorsed by APEC Ministers and welcomed by APEC Economic Leaders, the APEC Mexico City Principles serve as the only international best practice guidance to strengthen ethical business practices in the biopharmaceutical sector. As such, they serve as a minimum foundation in assessing industry code alignment with high-standard ethical business conduct. Many industry associations with a code or code commitment have chosen to incorporate the entire text of the APEC Mexico City Principles, while others have adapted certain provisions to align with local requirements.

Among the associations with a code or code commitment that responded to the 2019 survey (38 of 56), the top provisions aligned with the APEC Mexico City Principles are promotional information and activities (100%) and interactions with healthcare professionals (97%) while the least are clinical trials (79%), support for continuing medical education (81%), and safety of medicines (81%). The alignment gap in clinical trials is likely the result of several associations representing members who are not engaged in such activities.

TOP 5 PROVISIONS OF THE APEC MEXICO CITY PRINCIPLES ALIGNED WITH INDUSTRY ASSOCIATION CODES OF ETHICS (PERCENTAGE OF SURVEY RESPONDENTS)



LOWEST 5 PROVISIONS OF THE APEC MEXICO CITY PRINCIPLES ALIGNED WITH INDUSTRY ASSOCIATION CODES OF ETHICS (PERCENTAGE OF SURVEY RESPONDENTS)

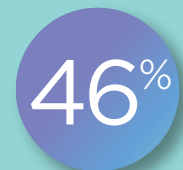


ACCELERATION IN CODE AMENDMENT

In order to drive code of ethics alignment with the APEC Mexico City Principles and high-standard ethical business practices, associations with an existing code must undertake amendments or issue parallel guidance. This year's survey has noted a significant increase in the number of associations planning code amendments within the next 12 months (46%). This is particularly significant when just 35% of associations have reported amending their code over the last two years. A likely factor contributing to this acceleration in code amendment includes the implementation of several updates to the Code of Practice by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).



ASSOCIATIONS AMENDING CODE OVER THE LAST 2 YEARS

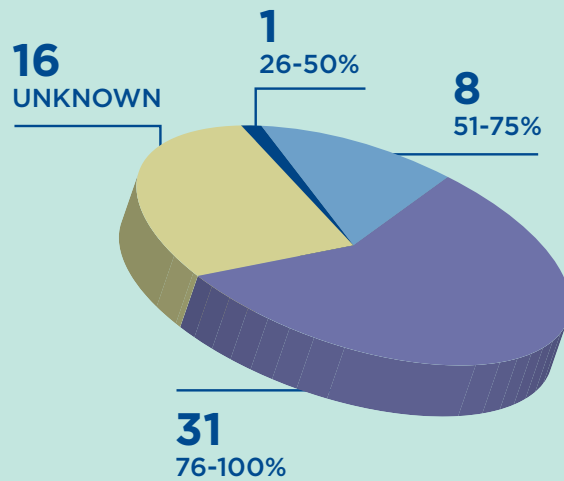


ASSOCIATIONS PLANNING CODE AMENDMENTS OVER THE NEXT YEAR

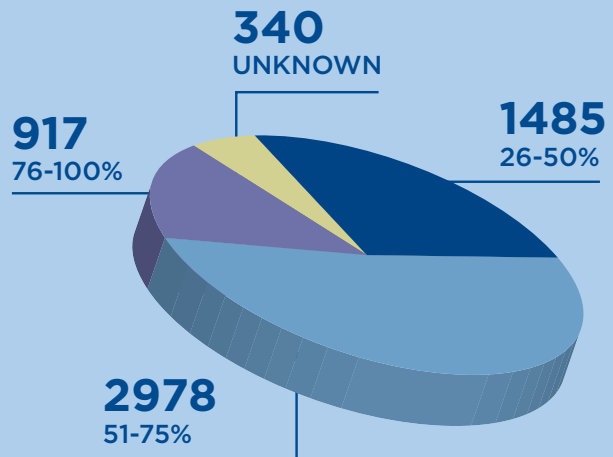
MEMBER ENTERPRISE IMPLEMENTATION

An association's code or code commitment is only effective if there is strong member enterprise implementation of code provisions into their daily business practices. The Nanjing Declaration calls upon every biopharmaceutical industry association in the APEC region with a code or code commitment to achieve at least 50% in member enterprise implementation. This Report seeks to measure member enterprise implementation based on estimates provided by each association. Among the 56 biopharmaceutical industry associations with a code or code commitment in the region, 31 (or 55%) estimate a member enterprise implementation rate between 76-100%. Importantly, these 31 associations only represent 900 of the region's more than 6,000 SMEs in the biopharmaceutical sector. An additional eight associations (or 14%) estimate a member enterprise implementation rate between 51-75%. These eight associations represent nearly 3,000 SMEs in the region's biopharmaceutical sector. Only one association estimates a member enterprise implementation rate of less than 50%, representing over 1,500 SMEs. The remaining 16 associations (or 29%) have an unknown rate of member enterprise implementation. This data seems to demonstrate a correlation between an association's SME membership size with a lower rate of member enterprise implementation. Further underscoring this finding, 83% of associations completing this year's survey reported they would find it helpful for the *Business Ethics for APEC SMEs Initiative* to offer a program for SME member companies' executive leaders to help them prioritize and implement ethical business practices as they oversee their organizations.

REPORTED MEMBER IMPLEMENTATION RATE BY THE 56 ASSOCIATIONS WITH A CODE / COMMITMENT



SME MEMBERSHIP OF REPORTED MEMBER IMPLEMENTATION RATE BY THE 56 ASSOCIATIONS WITH A CODE / COMMITMENT



NOTE: While 31 associations report member implementation rate of 76-100%, these associations only support 917 SMEs.

EXTERNAL ENGAGEMENT

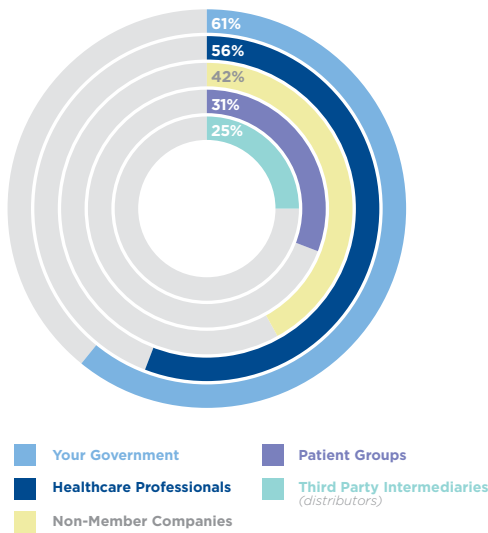
The extent to which biopharmaceutical industry associations and their members engage with external stakeholders across the health system is a key component to successful code implementation. This can include communication and collaboration on the code of ethics with governments, patients, healthcare professionals and providers, third party intermediaries, and non-member companies operating within the same marketplace.

Consensus Frameworks for ethical collaboration are emerging as a significant mechanism in the region for biopharmaceutical industry associations to engage with external stakeholders on codes of ethics. Since 2014, over 150 stakeholders across

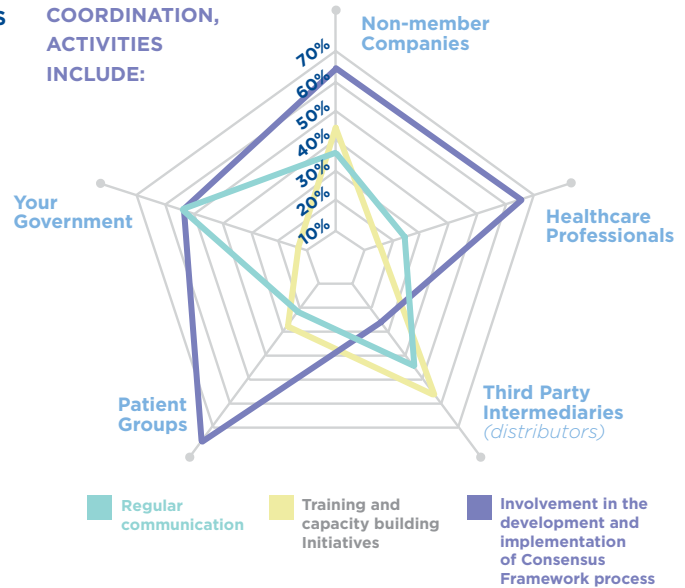
nearly a dozen APEC economies are actively utilizing or pursuing Consensus Frameworks to heighten collaboration on ethical business conduct. Consensus Frameworks are voluntary agreements by different parties within an economy to convene on a routine basis and facilitate actions that support ethical business conduct.

Associations' interest to heighten external stakeholder engagement on ethical business practices grew by 10% in 2019, to 81% of respondents, the highest recorded by the annual survey to date. However, coordination with non-member stakeholders in each category has declined since 2018, most significantly 15% with third party intermediaries.

COORDINATION WITH NON-MEMBER STAKEHOLDERS ON ETHICAL PRACTICES AND/OR YOUR CODE OF ETHICS



IF THERE IS COORDINATION, ACTIVITIES INCLUDE:



GOVERNMENT ENGAGEMENT

While it is necessary for governments to ensure consistent enforcement actions are taken against those who violate laws designed to prevent unethical business conduct, governments can also take proactive steps to encourage ethical business conduct before unethical conduct occurs.

94%

of associations are in support of the identification of government strategies to better support ethical business conduct.

PART 3

Code of Ethics Compendium

Association	Economy	Member Enterprises		Code Adoption <i>Code Commitment*</i>			Member Implementation	Participation in Consensus Framework Agreement
		TOTAL	SMEs	Yes/No	Year Adopt	Last Update		
Medicines Australia	Australia	34	9	Yes	1960	2015	76-100%	Yes
GBMA	Australia	7	4	Yes	2010	2016	76-100%	No
IMC	Canada	43	31	Yes	1988	2018	Unknown	Yes
CGPA	Canada	11	0	Yes	1998	2013	No Data	No
ASILFA	Chile	9	0	No	N/A	N/A	N/A	Yes
CIF	Chile	23	0	Yes	2006	2017	76-100%	Yes
Cámara Nacional de Laboratorios	Chile	12	10	Yes	2018	2019	76-100%	Yes
PROLMED	Chile	5	0	Yes	2018	2018	76-100%	Yes
CPIA	China	420	120	Yes	2013	2018	51-75%	Yes
CCCMHPIE	China	1,650	1,485	Yes	2013	2017	26-50%	Yes
PhIRDA	China	87	19	Yes	2018	2018	51-75%	Yes
RDPAC-CAEFI	China	43	0	Yes	1999	2019	76-100%	Yes
CATCM	China	700	500	Yes	2013	2015	76-100%	Yes
CAPC	China	384	249	Yes	2013	2015	51-75%	Yes
All-China Federation	China	No Data	No Data	Yes	2013	2015	No Data	No
CMBA	China	300	250	Yes	2015	N/A	No Data	Yes
CMEA	China	No Data	No Data	Yes	2015	N/A	No Data	No
CNMA	China	350	No Data	Yes	2013	2015	No Data	Yes
CPAPE	China	350	No Data	Yes	2015	N/A	No Data	Yes
CPEMA	China	No Data	No Data	Yes	2015	N/A	No Data	No
CPEP	China	150	No Data	Yes	2013	2015	No Data	Yes

Association	Economy	Member Enterprises		Code Adoption Code Commitment*			Member Implementation	Participation in Consensus Framework Agreement
		TOTAL	SMEs	Yes/No	Year Adopt	Last Update		
CPPA	China	No Data	No Data	Yes	2015	N/A	No Data	No
COAP	China	No Data	No Data	Yes	2015	N/A	No Data	No
CRAECC	China	No Data	No Data	Yes	2013	2015	No Data	No
HKAPI	Hong Kong, China	45	2	Yes	1971	2019	76-100%	No
HKPMA	Hong Kong, China	38	35	No	N/A	N/A	N/A	No
PDAHK	Hong Kong, China	44	44	No	N/A	N/A	N/A	No
GP Farmasi	Indonesia	2900	2300	Yes	2003	2016	51-75%	No
IPMG	Indonesia	26	16	Yes	2001	2017	76-100%	No
JPMA	Japan	72	5	Yes	1976	2019	76-100%	Yes
JGA	Japan	40	25	Yes	2010	2019	76-100%	Yes
KRPIA	Korea	44	33	Yes	2010	2018	76-100%	No
KPBMA	Korea	196	150	Yes	1994	2017	76-100%	No
KoBIA	Korea	107	50	No	N/A	N/A	N/A	No
MOPI	Malaysia	42	31	Yes	2013	2016	Unknown	No
PhAMA	Malaysia	46	0	Yes	1978	2019	76-100%	No
CANIFARMA	Mexico	95	0	Yes	2005	2018	76-100%	No
CETIFARMA	Mexico	101	76	Yes	2005	2019	76-100%	Yes
AMIIF	Mexico	43	12	Yes	2005	2018	76-100%	No
ANAFAM	Mexico	6	0	Yes	2005	2013	51-75%	No
ANADIM	Mexico	No Data	No Data	No	N/A	N/A	No Data	No
Medicines New Zealand	New Zealand	26	8	Yes	1962	2019	76-100%	No
ADIFAN	Peru	13	13	Yes	2014	N/A	76-100%	Yes
ALAFARPE	Peru	22	20	Yes	2016	2019	76-100%	Yes
ALAFAL	Peru	10	5	Yes	2016	N/A	76-100%	Yes
PCPI	Philippines	115	95	Yes	2014	2014	51-75%	Yes

Association	Economy	Member Enterprises		Code Adoption <i>Code Commitment*</i>			Member Implementation	Participation in Consensus Framework Agreement
		TOTAL	SMEs	Yes/No	Year Adopt	Last Update		
PHAP	Philippines	42	10	Yes	1993	2019	76-100%	Yes
MEPI	Philippines	46	0	Yes	2015	N/A	No Data	No
AIPM	Russia	44	14	Yes	1998	2016	76-100%	No
ARPM	Russia	20	0	No	N/A	N/A	N/A	No
SAPI	Singapore	39	0	Yes	<2010	2019	76-100%	No
SMF-LSIG	Singapore	48	30	No	N/A	N/A	N/A	No
IRPMA	Chinese Taipei	48	5	Yes	1994	2019	76-100%	No
TRPMA	Chinese Taipei	28	28	Yes	N/A	N/A	N/A	No
TPMA	Chinese Taipei	210	160	No	N/A	N/A	N/A	No
TGPA	Chinese Taipei	49	42	No	N/A	N/A	N/A	No
CAPA	Chinese Taipei	125	115	No	N/A	N/A	N/A	No
CPMDA	Chinese Taipei	50	16	No	N/A	N/A	N/A	No
NPCA	Chinese Taipei	No Data	No Data	No	N/A	N/A	N/A	No
TPADA	Chinese Taipei	8	0	No	N/A	N/A	N/A	No
TPMMA	Chinese Taipei	55	55	No	N/A	N/A	N/A	No
PRema	Thailand	37	0	Yes	1986	2019	76-100%	No
TPMA	Thailand	67	60	Yes	2015	2019	51-75%	No
GPO	Thailand	1	0	Yes	2015	N/A	76-100%	No
PhRMA	United States	35	0	Yes	2002	2009	76-100%	No
AAM	United States	24	No Data	Yes	2018	2018	Unknown	No
VNPCA	Viet Nam	177	135	Yes	2014	2018	51-75%	Yes
Pharma Group	Viet Nam	23	0	Yes	2014	2018	76-100%	Yes
IQGx	Viet Nam	9	0	Yes*	2016	2019	76 -100%	Yes
FIFARMA	Regional	13	0	Yes	2014	2019	76-100%	No
ALIFAR	Regional	N/A	N/A	No	N/A	N/A	N/A	No



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